

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NO. 11-md-02242-RWZ

IN RE: PROGRAF ANTITRUST LITIGATION

ORDER

February 12, 2013

ZOBEL, D.J.

Plaintiffs, direct and indirect purchasers of prescription drugs, filed suit against Astellas Pharma US, Inc. (“Astellas”), a pharmaceutical manufacturer and maker of Prograf, a branded prescription immunosuppressant (tacrolimus) used in organ transplant patients. Plaintiffs allege that Astellas filed a baseless citizen petition with the Food and Drug Administration, with the sole intent of foreclosing market entry by generic competitors, that improperly extended its monopoly and kept Prograf prices at supra-competitive levels. Several pending discovery motions are ripe for decision.

I. Astellas’ Motion to Compel Indirect Purchaser Plaintiffs to Produce New HIPAA Releases (Docket # 97)

Astellas moves to compel the two individual indirect purchaser plaintiffs – Judith Carrasquillo and Janet M. Paone (collectively, “consumer plaintiffs”) – to provide HIPAA¹-compliant releases that specifically authorize third parties (such as physicians, hospitals, and medical care facilities) to produce the following categories of information

¹ Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, 119 Stat. 1936 (Aug. 21, 1996).

from consumer plaintiffs' medical, prescription, and insurance claims records:

- Records of prescriptions for Tacrolimus-Containing Drug Products ("TCDPs")—a term which hereafter shall mean any dosage strength of PROGRAF® and any AB-rated generic tacrolimus products (including Hecoria ®);²
- Documents concerning the reason(s) why the patient was prescribed a TCDP and why he or she was prescribed one formulation of TCDP rather than another;
- Documents concerning the substitutability of different formulations of TCDPs;
- Documents concerning the testing of the patient's blood levels of tacrolimus, including the results of, and any claims and billing records related to, such testing;
- Documents concerning the circumstances and/or effects of switching by the patient among different formulations of TCDPs;
- Documents reflecting or concerning assistance, advice, or guidance provided to the patient (such as through a transplant coordinator or patient assistance program) concerning health care insurance coverage for, or financial assistance in obtaining, Prograf or AB-rated generic tacrolimus products; and
- Communications between the patient and his or her health care providers or transplant facilities or centers concerning Prograf or AB-rated generic tacrolimus products.

Astellas asserts that the requested information is relevant to issues of both liability and damages. Namely, Astellas anticipates that documents regarding consumer plaintiffs' medical treatment and experiences with Prograf and generic tacrolimus may reflect the very concerns raised in its citizen petition and thus rebut plaintiffs' allegation that the petition was "objectively baseless." Astellas also claims that evidence of fewer benefits, complications, or increased blood-level monitoring due to switching from the

² Each consumer plaintiff has already provided Astellas with HIPAA releases permitting the release of documents "concerning [her] prescription drug history as to PROGRAF® (tacrolimus) and any other tacrolimus-containing drug product, as well as the terms of [her] medical and prescription drug insurance coverage."

branded drug to generic formulations will bear directly on consumer plaintiffs' damage claims.

Consumer plaintiffs contend that the requested information is confidential and protected under state physician-patient privilege laws and HIPAA. They also dispute the relevance of the requested information, arguing that their medical records have no bearing upon the objective baselessness of the citizen petition since many of the documents will post-date the petition and Astellas has not shown that it was consulting with either consumer plaintiffs or their treating physicians at the time of filing. Consumer plaintiffs further maintain that since the damages sought will consist simply of overcharges calculated through economic models, discovery regarding their individual medical records in search of potential damages "offsets" is unnecessary and improper.

To the extent that the requested documents reveal information echoing the issues Astellas raised in the citizen petition, they may have some relevance to the objective prong of the "sham exception" to the Noerr-Pennington doctrine, a central matter in this case. However, consumer plaintiffs assert that the physician-patient privilege laws of their home states prohibit the requested discovery of their medical records. Because the indirect purchaser plaintiffs' action is based on diversity jurisdiction, state law on privileges governs this dispute. Fed. R. Evid. 501 ("[I]n a civil case, state law governs privilege regarding a claim or defense for which state law supplies the rule of decision."). Here, the applicable state law is that of Illinois for

Carrasquillo and Minnesota for Paone.³

Illinois has a statutory physician-patient privilege which provides that “no physician or surgeon shall be permitted to disclose any information he or she may have acquired in attending any patient in a professional character, necessary to enable him or her professionally to serve the patient” unless one of several enumerated exceptions applies. 735 ILL. COMP. STAT. 5/8-802 (2009). Similarly, under Minnesota law, “[a] licensed physician or surgeon, dentist, or chiropractor shall not, without the consent of the patient, be allowed to disclose any information or any opinion based thereon which the professional acquired in attending the patient in a professional capacity, and which was necessary to enable the professional to act in that capacity.” MINN. STAT. § 595.02 subd. 1 (2012). Both states’ privacy protections apply to patient medical records. See Kraima v. Ausman, 850 N.E.2d 840, 844 (Ill. App. Ct. 2006) (“A patient’s medical records, even when relevant, are generally entitled to protection from discovery under the physician-patient privilege.”); State v. Poetschke, 750 N.W.2d 301, 304 (Minn. Ct. App. 2008) (“[M]edical records traditionally fall within the scope of the physician-patient privilege.”).

Neither consumer plaintiff has consented to the disclosure of her medical

³ State laws regarding the privacy of individually identifiable health information are not preempted by HIPAA where they are “more stringent” than HIPAA’s privacy rule. 45 C.F.R. § 160.203(b). A state privacy standard is “more stringent” if it “prohibits or restricts a use or disclosure in circumstances upon which such use or disclosure otherwise would be permitted” under HIPAA. Id. § 160.202. Of relevance here, HIPAA’s regulations would allow a hospital to disclose patient medical records in a judicial proceeding pursuant to a court order or discovery request (subject to certain conditions), even without the consent of the patient. Id. § 164.512. Such a disclosure would not be permitted by Illinois’ and Minnesota’s more restrictive physician-patient privilege laws. See subsequent discussion on statutes infra. Thus, the pertinent state laws are not preempted by HIPAA and its regulations.

records.⁴ The only other relevant exception to both statutory physician-patient privileges is when a patient waives the privilege by placing his or her physical or mental condition at issue in a lawsuit. See 735 ILL. COMP. STAT. 5/8-802(4) (2009); MINN. STAT. § 595.02 subd. 5 (2012); Minn R. Civ. P. 35.03. Yet unlike in a medical malpractice or personal injury suit, it is difficult to see how the circumstances of this antitrust case give rise to the conclusion that consumer plaintiffs have placed their medical conditions at issue beyond their tacrolimus prescription drug history, for which releases have already been provided. Astellas has offered no persuasive argument to the contrary. Absent good reason to overcome consumer plaintiffs' statutory privileges, Astellas' motion must be denied.

II. Astellas' Motion to Compel Responses to Astellas' Second Set of Interrogatories (Docket # 104)

Astellas seeks to compel plaintiffs to provide responses to its second set of interrogatories. At a telephonic status conference with the parties on January 10, 2013, I noted that the motion would be allowed, effective 90 days after the close of discovery concerning class certification. Since the parties indicated at that conference that discovery on class certification was substantially complete, it was agreed that the 90 days would commence immediately. Therefore, plaintiffs shall produce responses

⁴ Astellas suggests that consumer plaintiffs waived their ability to assert their state physician-patient privileges or HIPAA protections by failing to object specifically on those grounds to Astellas' discovery requests for medical record information. However, in their responses, consumer plaintiffs did include a general objection to the requests "to the extent they seek information that is confidential or private in nature, that is covered by . . . the medical records privileges of the state in which the patients and records are located, the Health Information Portability and Accountability Act of 1996, . . . or any other applicable privilege, rule, or doctrine." See Docket # 101, Exs. C and D. They also objected to specific requests for medical records "to the extent [they] seek[] information and documents which is [sic] protected from disclosure by . . . applicable privilege." Id. Therefore, consumer plaintiffs have sufficiently preserved their objections to the discovery sought.

to Astellas' second set of interrogatories by April 10, 2013.

III. Plaintiffs' Motion to Compel Production of Documents from the Files of Toshinari Tamura and Yoshihiko Hatanaka, and Deposition Dates (Docket # 129)

Plaintiffs seek the production of documents from the custodial files of Toshinari Tamura, former Executive Vice-President and Chief Scientific Officer of Astellas Pharma Inc. (Astellas' parent corporation), and Yoshihiko Hatanaka, former President and Chief Executive Officer of Astellas. Plaintiffs also request that Astellas provide deposition dates for both Tamura and Hatanaka. However, plaintiffs have not adequately demonstrated the relevance of their requests. The motion will be denied without prejudice and may be reasserted upon a showing that either Tamura or Hatanaka was substantially involved in the filing of Astellas' citizen petition.

IV. Conclusion

Astellas' motion to compel indirect purchaser plaintiffs to produce new HIPAA releases (Docket # 97) is DENIED. Astellas' motion to compel responses to its second set of interrogatories (Docket # 104) is ALLOWED. Plaintiffs' motion to compel (Docket # 129) is DENIED.

February 12, 2013

DATE

/s/Rya W. Zobel

RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE